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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/966,036	09/28/2001	Dorrie M. Happ	50623.132	4580

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EXAMINER

FUBARA, BLESSING M

ART UNIT	PAPER NUMBER
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1618

DATE MAILED: 06/14/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/966,036

Applicant(s)

HAPP, DORRIE M.

Examiner

Blessing M. Fubara

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 30 March 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 2-5, 7-11, 14-17, 19, 21 and 23-48 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 2-5, 7-11, 14-17, 19, 21 and 23-48 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

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### **DETAILED ACTION**

Examiner acknowledges receipt claim amendments and remarks filed 3/30/06. Claims 2-5, 7-11, 14-17, 19, 21 and 23-48 are pending. Claims 5, 8, 9, 15, 19, 26, 28, 33 and 46 are amended.

#### ***Response to Amendment***

Applicant has amended to claims to recite that the "light- and/or UV- protective compound has no or substantially no therapeutic effect." However, that limitation is not taught in the specification and raises the issue of new matter because the specification at paragraph [0052] of the published application states that the UV-protective compound should be biocompatible and inert to the drug of the polymer layer and that the compound may optionally have therapeutic effect. Furthermore, dependent claims 11, 24, 30, 31, 35, 38 and 48 recite gold as the UV protective compound. Also substantially no therapeutic effect is not a zero therapeutic effect. The rejection is maintained as described below.

#### ***Claim Rejections - 35 USC § 103***

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 2-5, 7-11, 14-17, 19, 21 and 23-48 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Llanos et al. (US 6,746,773).

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Llanos discloses coating composition and method of coating medical composition with the coating composition where a first layer is top coated with a top coating layer; both coating layers contain polymer and drugs (abstract; column 2, lines 25-36; column 6, lines 19 to column 8 line 21; Examples 1-8). Paclitaxel, vincristic and actinomycin D are some of the drugs used in the coating composition (column 6, lines 52, 53 and 55). Llanos contemplates coating medical device such as stent (see Figure 4). Paclitaxel, vincristic and actinomycin D are recited in claim 4 as light sensitive drugs.

Llanos does not disclose the ratio of the UV-protective compound to polymer in the topcoat. Regarding the thickness of the layer, it is not inventive to determine how thick the layer is without showing the criticality of the thickness. There is no demonstration in applicant's specification showing that certain amount of the light or UV-protective compound relative to certain amount of the polymer in the top-coating composition provides unusual results to the coated medical device. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to coat a medical device with a coating composition that contains drug and polymer and to top-coat the initial-layers with a composition that contains drug, polymer and gold as disclosed in Llanos. One having ordinary skill in the art would have been motivated to use amounts of the light or UV-protecting and polymer in mass ratios appropriate to provide the desired effect.

### ***Response to Arguments***

3. Applicant's arguments filed 3/30/06 have been fully considered but they are not persuasive.

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Regarding applicant's argument that the gold of Llanos is therapeutically active, it is noted that:

a) the claims states either no or substantially no therapeutic activity and substantially no therapeutic activity is not zero therapeutic activity.

b) Dependent claims 11, 24, 30, 31, 35, 38 and 48 recite gold as the UV protective compound.

c) The claims are thus not patentable over Llanos.

4. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Shanton (US 5,776,619) discloses coating composition that contains polymer and UV-protective compounds (abstract and claims 1-29).

***Claim Rejections - 35 USC § 112***

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 2-5, 7-11, 14-17, 19, 21 and 23-48 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is new matter rejection.

The as filed specification does not support for "light- and/or UV- protective compound has no or substantially no therapeutic effect." The only support is at paragraph [0052] of the published application for a UV-protective compound that should be biocompatible and inert to the drug of the polymer layer and that should optionally have therapeutic effect.

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Applicants may overcome this rejection by removing the new matter from the claims.

Claim Objections:

Claims 11, 24, 30, 31, 35, 38 and 48 are objected to for improperly depending from claims that require no therapeutic activity for the protective compound. Applicant in the remarks states that the polymer layer having the UV-protective compound cannot have gold as the UV-protective compound.

Correction is respectfully required.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Blessing M. Fubara whose telephone number is (571) 272-0594. The examiner can normally be reached on 7 a.m. to 5:30 p.m. (Monday to Thursday).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Blessing Fubara  
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